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VIA EMAIL

September 12, 2022

The Honorable Evelyn Padin, U.S.D.J.
United States District Court
Martin Luther King, Jr. Federal Building
50 Walnut Street
Newark, New Jersey 07102

Re: Corcept Therapeutics, Inc. v. Hikma Pharmaceuticals USA, Inc.
Civil Action No. 21-5034 (EP)(LDW)

Dear Judge Padin:

This firm, together with Quinn Emanuel, represents Plaintiff Corcept Therapeutics, Inc. (“Corcept”) in the above-referenced matter. We write on behalf of Corcept and Defendant Hikma Pharmaceuticals USA, Inc. (“Hikma”) in response to Your Honor’s August 29, 2022 order requesting a joint letter regarding the status of the case. *See* ECF No. 54.

We provide further information below.

1. Summary of the Claims and Defenses

This is a patent infringement case arising from Hikma filing an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market a generic version of Corcept’s 300 mg mifepristone drug product prior to the expiration of United States Patent Nos. 10,195,214, 10,500,216, 10,842,800, and 10,842,801 (together, “the patents-in-suit”), owned by Corcept. *See generally* ECF No. 1. Hikma seeks FDA approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Hikma’s generic mifepristone product before the patents-in-suit expire, which Corcept alleges is an act of patent infringement under 35 U.S.C. § 271. Hikma denies these allegations. *See* ECF No. 9. Hikma has asserted counterclaims, seeking declaratory judgments that the patents-in-suit are (1) not infringed and (2) invalid or unenforceable. *See id.* Corcept denies that Hikma is entitled to the relief sought in its counterclaims. *See* ECF No. 16.

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2. Status of Discovery

The parties have substantially completed their document productions, and there are no fact discovery disputes pending before the Court. Under the Court's Pretrial Scheduling Order (ECF No. 21), fact discovery was scheduled to close on July 1, 2022.

There is no deadline for the parties to exchange expert reports. *See* ECF No. 21 (ordering that "expert reports shall be delivered by **a date to be determined**").

3. Pending Motions

In accordance with the Court's scheduling orders (ECF Nos. 21 and 32), the parties have fully briefed their sole claim construction dispute. *See* ECF Nos. 37, 38, 47, 48.

This is the only briefing currently pending before the Court.

[REDACTED]

5. Other Issues to Be Addressed

[REDACTED] the parties intend to address at that conference a schedule for the remainder of this action.

* * *

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,

William C. Baton

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cc: All counsel of record (via email)